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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,895	11/17/2003	Jean-Louis Dasseux	9196-030-999	5269

20583 7590 02/27/2007

JONES DAY
222 EAST 41ST ST
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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	**PAPER NUMBER**
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,895	DASSEUX ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

1. The non-final Office action, mailed 10/12/2006, contained a wrong page 4. Therefore, the Office action, mailed 10/12/2006, is withdrawn and is replaced by the non-final Office action that follows below. The period for reply is re-started. The examiner regrets any inconvenience this accident may have caused the applicant.

2. Claims 57-79 are pending and examined.

Nucleotide and/or Amino Acid Sequence Disclosure

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the *attached* Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In particular, the stated total number of SEQ ID (stated as 254) found on the paper copy of the sequence listing does not agree with the number of the last SEQ ID, which is 258. Furthermore, the entries for SEQ ID No.s 233-236 fail to identify any nucleotide or amino acid sequence, at all. Applicant is required to comply with the

corrections for the sequence listing as per above as part of a complete response to this official action.

Election/Restrictions

4. Applicant's election of species in the reply filed on 7/26/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5. Because the elected species are not found in the prior art, the examiner has extended the search of the prior and has examined herein the elected and non-elected species. Therefore, the requirement for election of species, as set forth in the Office action mailed 6/26/2006, is withdrawn.

Priority

6. This application, filed 11/17/2003, states that it is a continuation of 09/453,840, filed 12/01/1999, now US Patent 6,716,816; which is a divisional of 08/940,095, filed 9/29/1997, now US Patent 6,004,925.

Claim Objections

7. Claim 79 is objected to because of the following informalities: Claim 79 depends from claim 88; however there is no claim 88. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 57-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 57 states: "Peptide PVLDLFRELLNELLEALKQKLK (SEQ ID NO: 4)." The Specification at p. 17, lines 30-33, states that "[t]peptides of the invention were designed based on the supposed helical structure and amphipathic properties of the 22 amino acid consensus sequence which was derived from the helical repeats of ApoA-I." Thus claims 57-62 appear to encompass a product of nature, and so are non-statutory subject matter.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 57-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent, base Claim 57 does not recite a connecting term, such as "consisting of" or "comprising", etc., so that relationship of the claim term "[p]eptide" to

the claimed amino acid sequence of SEQ ID 4, is vague and indefinite. Therefore one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 57-79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

a. claims 1-23 of US 6,844,327;

b. claims 1-48 of U.S. Pat. No.6,753,313;

c. claims 1-58 of U.S. Pat. No. 6,716,816;

d. claims 1-36 of U.S. Pat. No. 6,630,450;

e. claims 1-38 of U. S. Pat. No. 6,602,854;

f. claims 1-34 of U.S. Patent No. 6,573,239;

g. claims 1-48 of U.S. Patent No. 6,573,239;

h. claims 1-9 of U.S. Pat. No. 6,518,412;

i. claims 1-21 of U.S. Pat. No. 6,376,464;

j. claims 1-21 of U.S. Pat. No. 6,329,341;

k. claims 1-49 of U.S. Patent No. 6,046,166

l. claims 1-54 of U.S. Patent No. 6,037,323; and

m. claims 1-58 of U.S. Pat. No. 6,004,925.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention, drawn to a peptide that is SEQ ID 4, peptide-lipid complexes, pharmaceutical compositions, and methods of treatment thereof are obvious over the claims in the above-cited patents, which teach pharmaceutical compositions comprising Apo-A1 agonist peptide compounds comprising 15-29 residues comprising charged residues (e.g. 3-5) and hydrophobic residues (e.g. 40-70%) within the scope of the presently claimed invention which further form peptide-lipid complexes, pharmaceutical compositions thereof, and methods of treating various diseases by methods comprising administering Apo-A1 agonist peptide compounds.

14. Claims 57-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

a. claims 76, 78-103 of copending Application No.09/865,989 (PG PUB: 2004/0029807 A9);

b. claims 1, 3-17 and 36 of copending Application No.10/099,574 (PG PUB: 2003/0060604A1);

c. claims 1, 3-8, 12-17, 29, 34, 35, 37, 42, and 57 of copending Application No. 10/099,836 (PG PUB 2003/0203842A1);

d. claims 53-58, 60-83 of copending Application No.10/801,897 (PG PUB: 2004/0198662A1);

e. claims 1, 19-21, 28, 36, 41, 43-46, 53 and 56-57 of copending Application No.10/937,767 (PG PUB: 2005/0080013 A1; and

f. Claims 1, 19-21, 28, 36, 41, 43-46, 53, 56 and 57 of copending Application No.11/482,292.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention, drawn to a peptide that is SEQ ID 4, peptide-lipid complexes, pharmaceutical compositions, and methods of treatment thereof are obvious over the claims in the above-cited copending applications, which teach pharmaceutical compositions comprising Apo-A1 agonist peptide compounds comprising 15-29 residues comprising charged residues (e.g. 3-5) and hydrophobic residues (e.g. 40-70%) within the scope of the presently claimed invention

which further form peptide-lipid complexes, pharmaceutical compositions thereof, and methods of treating various diseases by methods comprising administering Apo-A1 agonist peptide compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. Claims 57-79 are rejected.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya, Ph.D.
Primary Examiner
Art Unit 1639

Notice to Comply	Application No.	Applicant(s)
	10/715,895	Dasseux
	Examiner	Art Unit
	SHIBUYA	1639

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Please see attached ~~sheet~~. Office action.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
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